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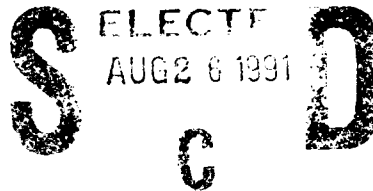


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TESTING AND EVALUATION OF THE MEDICAL TECHNOLOGY PRODUCTS MODEL 1001a INFUSION PUMP

Thomas E. Philbeck, Jr., Master Sergeant, USAF

December 1990

Final Report for Period November 1988 - April 1990

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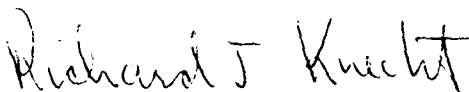
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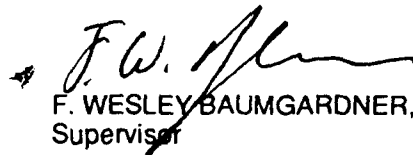
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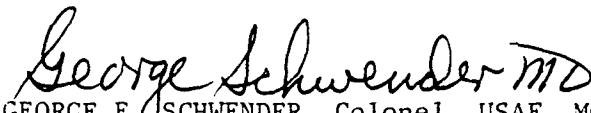
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RICHARD J. KNECHT, Lieutenant Colonel, USAF, NC
Project Scientist



F. WESLEY BAUMGARDNER, Ph.D.
Supervisor



GEORGE E. SCHWENDER, Colonel, USAF, MC, CFS
Commander

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The Military Airlift Command directs and controls aeromedical evacuation missions for the United States Air Force (USAF) and most of the Department of Defense (DOD). There is often a critical need to monitor and control the rate of infusions of intravenous fluids being administered to patients. The aeromedical evacuation system has, for the past several years, utilized the IMED Volumetric Pump Model 928. At present, the 928 is no longer being manufactured. The MTP Model 1001a is the selected replacement. The Aeromedical Research Function at the USAF School of Aerospace Medicine tested and evaluated the Model 1001a, and found that it is a safe and reliable device for the delivery of intravenous fluids, and is acceptable for worldwide aeromedical evacuation use.

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TABLE OF CONTENTS

	<u>Page</u>
BACKGROUND.....	1
DESCRIPTION.....	1
METHODS.....	2
Performance Checks.....	3
Baseline Performance Assessment.....	6
Electromagnetic Interference.....	7
Vibration.....	8
Environmental.....	8
Altitude.....	9
Airborne Feasibility.....	10
Battery and Charging Testing.....	13
Operation on 400 Hertz.....	13
RESULTS.....	14
Baseline Performance Assessment.....	14
Electromagnetic Interference.....	17
Vibration.....	18
Altitude.....	24
Airborne Feasibility.....	25
Battery and Charging Testing.....	27
Operation on 400 Hertz.....	27
REQUIREMENTS AND RECOMMENDATIONS.....	29
CONCLUSIONS.....	32
ACKNOWLEDGMENTS.....	33
REFERENCES.....	33



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List of Illustrations

<u>Fig. No</u>		<u>Page</u>
1.	The MTP Model 1001a Infusion Pump	1
2.	Basic test setup	3
3.	Infusion rate test setup.....	4
4.	Vibration test setup.....	9
5.	Battery bracket following initial vibration.....	19
6.	Battery assembly following initial vibration.....	19
7.	Power cable assembly following initial vibration.....	20
8.	MTP Delivery Set at 50 ml/h During Vibration Testing	21
9.	MTP Delivery Set at 150 ml/h During Vibration Testing.....	22
10.	MTP Delivery Set at 499 ml/h During "Z" Axis.....	22
11.	MTP Delivery Set at 499 ml/h During "X" & "Y" Axes	23
12.	Mounting on the C-9 aircraft using the Aeromedical Equipment Securing Pole.....	26
13.	Mounting on the C-141 aircraft using the Aeromedical Equipment Securing Pole.....	27
14.	Voltage during battery operation and charging on 110 VAC	28
15.	Voltage during battery operation and charging on 110 VAC, post rapid decompression testing.....	28
16.	Temperature of transformer/charger during 400 Hz operation	29

List of Tables

<u>Table No.</u>		
1.	Volume Infused Accuracy.....	15
2.	Flow Rate During 22-h Operation Period (Rate: 150 ml/h)	16
3.	Dependability of Air-In-Line Detector at 10,000 Ft Altitude.....	24

TESTING AND EVALUATION OF THE MEDICAL TECHNOLOGY PRODUCTS MODEL 1001a INFUSION PUMP

BACKGROUND

The United States Air Force Military Airlift Command (MAC) directs and controls aeromedical evacuation missions for the USAF and most of the Department of Defense (DOD). There is often a critical need to monitor and control the rate of infusion of intravenous fluids being administered to patients. The aeromedical evacuation system, whose command and control is received from the 375th Military Airlift Wing (MAW) at Scott AFB IL, has primarily used the IMED Volumetric Infusion Pump, Model 928 for the past several years. At present, the Model 928 is no longer being manufactured. The MTP Model 1001a Infusion Pump, manufactured by Medical Technology Product Inc of Huntington NY, is the selected replacement (Fig. 1).



Figure 1. The MTP Model 1001a Infusion Pump.

DESCRIPTION

The pump is comprised of a microcomputer-controlled stepper motor-driven pump and a disposable intravenous (IV) pump set for IV therapy. The pump works on a rotary peristaltic pumping principle, acting on a disposable pump chamber. The chamber has dimensional tolerances permitting it to deliver a precise volume of fluid. The disposable IV pump sets have patented keyed connectors which ensure proper installation during setup. The pump operates on 110-120 volt AC, 50-400 Hz, or on its own self-contained rechargeable gel-celled 6-v battery. Controls include flow and

total volume, and a standby switch to be used before changing either of the other 2 controls. Safety features include a self-test and tamper, low battery, air sensor, and occlusion alarms. The visual display directs setup sequence, flags user errors before infusion begins, provides visual alarms, displays actual volume infused; and when in a keep-vein-open (KVO) mode, alternates "KVO" with actual volume infused. The pump is 17.8 cm x 11.4 cm x 10.8 cm (7.0 in. x 4.5 in. x 4.25 in.), and weighs 2.1 kg (4.7 lb).

METHODS

1. Test methods and performance criteria used were derived from various military standards, nationally recognized performance guidelines, and the manufacturer's literature. The Aeromedical Research Function develops testing procedures that cover safety and human factor issues regarding the equipment to be tested. A "performance check" is developed that verifies proper functioning of the equipment under various conditions.

2. The device is then subjected to various tests to check its performance under various anticipated operational conditions. The following tests generally involve a repetition of the performance check under specified conditions:

- a. Baseline Performance Assessment
- b. Electromagnetic Interference (EMI)
- c. Vibration
- d. Altitude, encompassing:
 - (1) Hypobaric chamber testing
 - (2) Rapid decompression testing
- e. Airborne Feasibility

3. Test Setup: The basic test setup included an MTP IV set attached to an IV solution bag, installed and threaded through the MTP pump head assembly, with the patient end connected to an IV extension set (Fig. 2). The patient end of the extension set was looped and spiked into the same IV solution bag through the injection port. These components formed a continuous loop pathway for the IV solution to travel when the MTP was in operation. Specifically, the following components were used to assemble the basic test setup (Some tests required modified versions of the basic test setup. Those versions will be described in the appropriate sections.):

- a. Travenol Intravenous Solution, 0.9% Sodium Chloride, 1,000 ml.
- b. Medical Technology Products Inc Universal IV Standard Pump Set, Model 1200.
- c. Pharmaseal K52 Novex 3-Way Stopcock, With Extension Tube.



Figure 2. Basic test setup.

Performance Checks

The established performance check enabled us to evaluate each function and alarm featured on the MTP. The performance check was conducted as follows:

1. Infusion Rate:
 - a. Rates of 50, 150, and 499 (the maximum) ml/h were checked, 6 times each.
 - b. Test setup: See Figure 3.
 - (1) Basic Test Setup
 - (2) Neurodyne-Dempsey Model 404A IV Analyzer

(3) Neurodyne-Dempsey volumetric chambers

(a) Model 404-3X5A (3.5 ml capacity)

(b) Model 404-35A (35 ml capacity)

(4) 3-way Stopcock

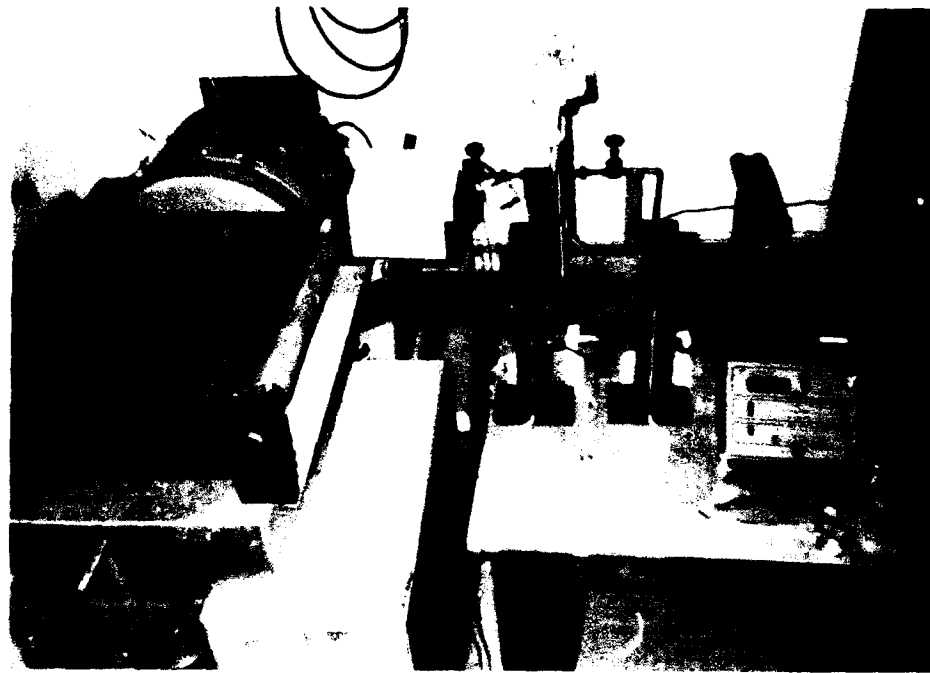


Figure 3. Infusion rate test setup.

2. Total Volume To Be Infused:

a. With the MTP infusion rate set at 50 ml/h, the "total volume to be infused" was set at 50 ml. The display, which shows a running total of the volume infused, was closely observed to determine if the "KVO" alarm activated when the volume infused reached 50 ml; and to see if the MTP actually entered the "KVO" mode. The volume infused was measured by infusing the fluid from a full IV bag to an empty one, and actually measuring the volume, using a graduated cylinder.

b. The procedure was repeated at infusion rates of 150 and 499 ml/h, with the total volume to be infused set at 50 ml.

c. The procedure was repeated at flows of 50, 150, and 499 ml/h and the "total volume to be infused" at 500 and 1,000 ml.

d. Test Setup: Basic

3. Keep-Vein-Open Rate:

a. The MTP Operation Manual (1) states that once the volume to be infused has been achieved, the MTP will activate the alarm, and automatically reduce to a KVO rate. If the original rate had been less than 5 ml/h, the KVO rate would be 0.5 ml/h; and if the original rate had been 5 ml/h or higher, the KVO rate would be 1.0 ml/h.

b. For test purposes, the original rate was set at 4 ml/h, and the volume to be infused was set at 50 ml. Once the 50 ml had been infused, and the MTP had gone into the KVO mode, a rate check was done using the Neurodyne-Dempsey IV analyzer.

c. Test Setup: As described in paragraph 1b, using the 404-3X5A volumetric chamber.

4. Air-In-Line Alarm:

a. The **Operation Manual** states that the pump's air detector will recognize and actuate the alarm when an air bubble 0.075 ml or larger passes the sensor. The **contract specifications** (2) require that the sensor detect air bubbles 0.050 ml or larger. With the air leak test setup attached to the basic test setup, the MTP was run at a rate of 50 ml/h. Using a Monoject tuberculin syringe and a Monoject 21 ga x 3.18 cm (1 1/4 in.) needle, 0.050 ml of air was introduced to the circuit 5 times through the prepump injection port, about 48.26 cm (19 in.) from the pump head inlet. The MTP was observed to determine if the Air Leak Alarm was activated as the bubble passed the sensor. The number of times the MTP's alarm was activated was recorded. If the unit failed to activate even once out of the 5 samples injected, then 5 more samples were introduced, and results recorded. Then, 0.075 ml of air was introduced 5 times in the same manner. The number of times the alarm was activated was recorded. The entire procedure was repeated with the rate set at 150 ml/h and 499 ml/h.

b. Test Setup: Basic

5. Occlusion Alarm:

a. Using plastic clamps, the tubing was occluded by clamping 2.54-5.08 cm (1-2 in.) past the 3-way stopcock on the K52 tubing leading to the drain bag. When the occlusion alarm was activated, (displayed as "OCC"), the pressure meter display reading was recorded. At each rate setting (50, 150 and 499 ml/h), the occlusion test was performed 5 times.

b. Test Setup: A 3-way stopcock was placed inline with the basic test setup at the point where the pump set is connected to the K52 tubing. An additional K52 extension tube was attached to the 3-way stopcock, which led to a Bio-Tek Universal Biometer (pressure meter), Model DPM-III.

Baseline Performance Assessment

1. Purpose: The primary purpose of the Baseline Performance Assessment (BPA) is to quantitatively measure and document the IV pump's performance under standard ambient conditions (73 ± 17 °C, 760 ± 50 mmHg barometric pressure, $50 \pm 3\%$ relative humidity) before adverse testing. The BPA will be used as a reference to measure subsequent performance, verify selected manufacturer and contract specifications, and to ensure safe operation and use before testing. The procedures used were derived from portions of the Emergency Care Research Institute (ECRI) Health Care Devices bulletin (3); AFR 160-3, Electrical Safety in Medical Treatment Facilities (4), and the Operation Manual.

2. Test Equipment Used:

- a. Dempsey Electrical Safety Analyzer, Model 431F
- b. Power Supply, 0 to 15 VDC, 3 amp
- c. Fluke Multimeter, Model 8024B
- d. Squirrel Data Logger/Meter Model 1201
- e. Miscellaneous Wires for Connecting the Resistor to the Squirrel
- f. Bio-Tek Universal Pressure Meter, Model DPM-II
- g. IV Fluid, 5% Dextrose, 1,000 ml bags
- h. Brass Resistor Block, 5.2 milliohms
- i. Neurodyne-Dempsey IV Pump Analyzer, Model 404A
- j. Tape Measure
- k. 2,000-ml Flask
- l. 60-ml Syringe

3. Electrical Safety: The electrical safety check consisted of ground resistance, leakage current, strain relief testing, and a visual examination of the pump's wiring. Measurements were made using the Dempsey Electrical Safety Analyzer.

4. Alarms:

a. Air-In-Line: Verified by injecting 0.050 ml air into the IV line before the air-in-line detector. It should be noted the manufacturer's literature states an air detection sensitivity of 0.075 ml, and the contract specified 0.050 ml.

b. Infusion Complete: Verified by setting the volume to be infused at 1, 5, and 150 ml/h and ensuring that the "KVO" audio and visual indicators operate, with the volume infused alternately indicated on the display.

c. Occlusion: Verified by occluding the IV flow and measuring the in-line pressure. Pressure measurements were made using a Bio-Tek Model DPM II connected to a 3-way stopcock at the administration site. The flow was set at 100, 200, and 400 ml/h and the IV line occluded between the bag and pump.

d. Low Battery (Battery Operating/Charging Characteristics): Verified by fully discharging the battery ("BAT" alarm), charging the battery on 110 VAC/60 Hz for 24 h and operating the unit at a flow of 150 ml/h until the low battery alarm activated. The test was repeated after charging on 110 VAC/400 Hz for 24 h. During this test, the "AIR" alarm activated for about 4 h. Once the low battery alarm was activated, the start/stop switch was pressed twice to silence the alarm and allow continued infusion with "BAT" and amount infused displayed. The battery voltage and current were measured during these tests. Current measurements were calculated from a 5.2 milliohm resistor in series with the positive battery lead. Operation on line power with the battery out of circuit (open), or shorted, was verified by disconnecting and then shorting the unit's battery wires (not the battery) together and operating the unit on line power.

Electromagnetic Interference

1. Purpose: The purpose of EMI testing is to verify compliance with MIL-STD-461C, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference, Category A1e (5). The following 4 tests were conducted:

a. Radiated Emissions (RE-02): This test measures radiated emissions generated by the infusion pump during its operation. Both narrow-band and broad-band tests are performed. Excessive amounts could interfere with aircraft navigation and communication equipment.

b. Conducted Emissions (CE-03): This test measures emissions generated by the infusion pump and conducted through the aircraft power lines. This test must be performed to ensure that operating the pump using line power does not affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-02): This test determines whether the ambient electromagnetic fields (noise) encountered inflight interferes with the operation of the infusion pump. The pump was exposed to the electromagnetic fields described in USAFSAM Test and Evaluation Planning Guide for Aeromedical Evacuation Equipment (6).

d. Conducted Susceptibility (CS-06): This test determines whether the pump can withstand predefined levels of voltage spikes on its power lines.

2. Pre-Tests and Post-Tests:

- a. The MTP was checked for flow accuracy at rates of 5, 150, and 499 ml/h. Three checks were done at each rate.
- b. Alarms were checked as follows: Occlusion pressure (indicated as "OCC"), IV infusion complete/KVO (indicated as "KVO"), and air-in-line (indicated as "AIR").
- c. Battery voltage.

3. Test Procedures:

- a. For each EMI test, the MTP was operated on 60 Hz, 400 Hz, and internal battery.
- b. The pump was operated at 150 ml/h.
- c. The pump was operated with the IV infusion complete/KVO alarm activated.

4. Test Setup: Basic

Vibration

1. Purpose: Using MIL-STD-810D (7) as a guide, these tests consist of random and sinusoidal X, Y, and Z curves to test the MTP's construction, durability, and performance and the integrity of the mounting devices during worst case vibration scenarios. The Unholtz-Dickey Vibration Control Console and Vibration Table at the USAFSAM Engineering and Maintenance Services Branch (TSNB) was used for the tests.
2. Pre-Tests and Post-Tests: Visual examination and performance checks were conducted.
3. Test Setup: Using the mounting device provided by the manufacturer, the MTP was secured to a standard North Atlantic Treaty Organization (NATO) litter pole, and then bolted to a 6.35 mm (1/4 in.) metal plate. This setup was secured to the vibration table. (See Fig. 4.)
4. Test Procedures: The console and table were operated by technicians from TSNB, who programmed the control console for five 15-min cycles, totaling 75 min, on each axis for the sinusoidal testing; and 30 min on each axis for the random testing. During the tests the unit was closely observed, and infusion rate checks were conducted every 15 min. All functions and alarms normally evaluated as part of the performance check were evaluated at least once.

Environmental

Mission scenarios were discussed with the personnel from the MAC Surgeon's and the 375th Aeromedical Airlift Wing Surgeon's offices. Based on the intended

operational use of the MTP, we decided that environmental testing would not be conducted.

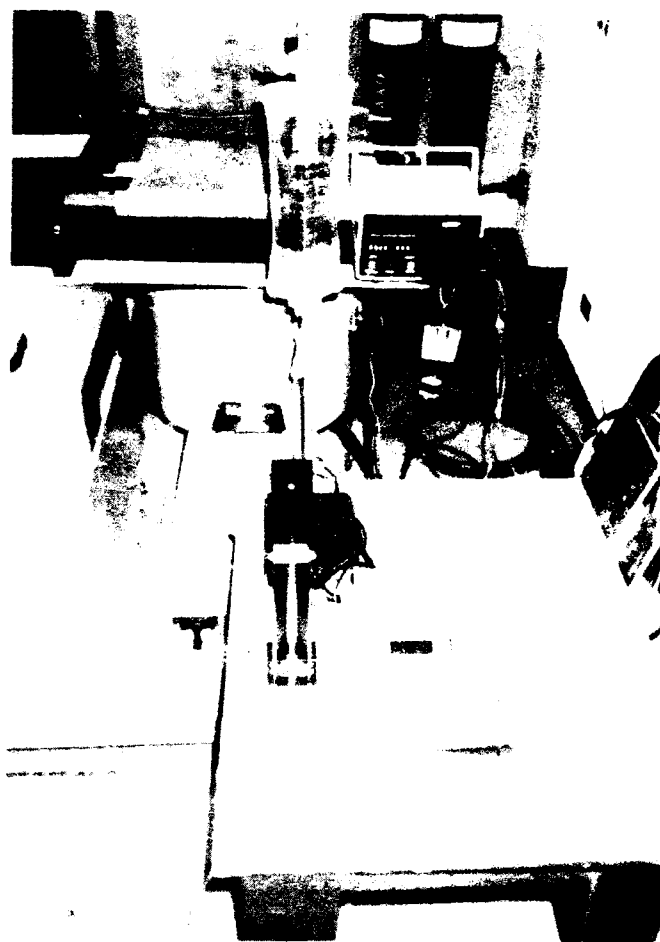


Figure 4. Vibration test setup.

Altitude

1. Hypobaric Chamber Testing: Testing was conducted in the research chambers; operated and monitored by chamber operations personnel assigned to the Systems Engineering Branch (USAFSAM/VNS) of the Crew Technology Division at USAFSAM. The MTP, with the various test setups, were set up inside the chamber. Pre-test and post-test performance checks were performed. Typically, at a rate of 5,000 ft per min, the chamber was depressurized to 10,000 ft equivalent (523 mmHg total pressure). While at altitude, standard performance checks were performed.
2. Rapid Decompression: As a pretest, an infusion rate check was performed. Battery voltage was also recorded, using the Grant Model 1201 Squirrel Logger/Meter. The IV fluid, tubing and test setup were removed from the MTP. The flow was set at 150 ml/h, and with the MTP running on battery power, the unit was placed in the chamber. The chamber was sealed, and depressurized to the equivalent of 8,000 ft. The unit continued to operate at this altitude for 5 min, and was observed through the door

window. Then, the chamber was depressurized to an equivalent of 40,000 ft, over a period of 60 s. The unit was observed. The chamber was pressurized to ground level. The MTP was removed. The MTP battery voltage was recorded and the flow check was performed. The unit was placed in the chamber, and the process was repeated twice, with the rapid decompressions occurring over intervals of 7 and 1 s.

Airborne Feasibility

This phase of testing was performed by 2 aeromedical research technicians, who were current and qualified as aeromedical evacuation crewmembers on the 2 aircraft used, the C-9A and the C-141B. Before actual airborne testing, the protocol was reviewed and discussed with the aeromedical research staff; and "dry runs" were made in the C-9A, C-130, and C-141B mockups in Building 820, Brooks AFB. The airborne feasibility testing started with C-9A aeromedical evacuation missions from Kelly AFB TX to Scott AFB IL to Charleston AFB SC, with 7 takeoffs, 7 landings, and about 8 h logged inflight. The aircraft was pressurized to 8,500 ft equivalent. Testing continued on a C-141B aeromedical evacuation mission from Charleston AFB to Howard AFB Panama to Kelly AFB, with about 10 h logged inflight. The aircraft cabin altitude was recorded at 9,500 ft equivalent.

1. Test/Support Items:

- a. Dynatech Nevada Model 404A IV Analyzer
- b. Model 404-35A and 404-3X5A Volumetric Chambers
- c. Biotek Instruments, Inc Universal Biometer, Model DPM-III
- d. Grant Squirrel Model 1201 Meter/Logger
- e. MTP IV Sets, Models 1200 and 1201
- f. IV Rate Test Setup
- g. Basic Test Setup
- h. Pressure Test Setup
- i. Air Test Setup
- j. 0.9% Sodium Chloride IV Solution, 500-ml Bags
- k. TB Syringes with 25 ga Needles
- l. Data Collection Sheets (DCS)
- m. Squirrel Humidity Probe & Temperature Probes (2 ea)
- n. Squirrel AC Adaptor

(2) Power/Charging Check:

(a) Set up MTP and ran on battery for half of the projected mission time. Logged voltage every 5 min using Squirrel. Logged manually every 30 min, annotating on DCS.

(b) For second half of mission time, plugged unit into aircraft power to ensure operability and charging capability. Logged voltage every 5 min using Squirrel. Logged manually every 30 min, annotating on DCS.

(3) Rate Check:

(a) Using IV analyzer and test setup, tested accuracy 3 times each at rates of 50, 150, and 499 ml/h.

(b) If 1 or more of the 3 tests results exceeded 100% (± 5) accuracy, conducted an additional 7 tests, (for a total of 10) at that rate.

(4) Air Bubble Test:

(a) Using bubble test setup, injected 0.075 ml inline, prepump, and observed MTP for air alarm activation. Did this procedure 3 times each at rates of 50, 150, and 499 ml/h.

(b) If 1 or more of the 3 bubbles did not cause alarm activation, injected 7 more (for a total of 10) bubbles, and recorded results on the DCS.

(5) Pressure Test:

(a) Using the pressure meter, and pressure test setup, occluded down-line from the air pressure port. Observed the monitor and recorded the pressure when the MTP pressure alarm activated.

(b) Accomplished 3 times each at rates of 50, 150, and 499 ml/h.

(c) Observed the tubing pump segment outlet for leakage during this test. If leakage occurred, noted on DCS and replaced tubing.

(6) Total Infused Test: Checked during the course of other testing procedures.

(a) Set infusion total at 25. Proceeded with other testing procedures as required.

(b) When 25 ml was infused, recorded on DCS whether MTP activated the alarm or not.

(c) Changed infusion total to 50. Repeated steps above for this and totals of 100, 200, 400, and 800 as time permitted.

Battery and Charging Testing

1. Background: Following the first series of vibration tests, it was realized that the battery and charging system were extremely vulnerable to damage resulting from vibration. Due to this vulnerability, specific tests were conducted to determine the MTP's battery duration, and charging requirements. Also, for the remainder of any other testing, the battery voltage was constantly monitored.

2. Setup: Monitoring was accomplished by the following method:

- a. The MTP outside casing was removed, exposing the battery assembly.
- b. Wires 22 awg x 24 in. were attached, 1 to the positive and 1 to the negative battery terminals. The other ends of the wires were fed through an opening in the casing, and the casing was reinstalled.
- c. The other ends of the wires were attached to a Grant Squirrel Meter/Logger for voltage reading and/or logging.

3. Method: The MTP was plugged into 110 VAC/60 Hz current for charging for 24 h. After the charging period, the charger was unplugged to allow the MTP to operate on the battery. The MTP was allowed to operate on the battery until the "BAT" alarm was activated, ending the test. Throughout this process the Squirrel was logging the voltage every 5 min. At the conclusion of the test, the data from the Squirrel was downloaded into a Macintosh computer for plotting, graphing, and subsequent analysis.

4. Equipment Used:

- a. Basic Test Setup
- b. Grant Squirrel Meter/Logger, Model 1201
- c. Wires from MTP battery to Squirrel

Operation on 400 Hertz

1. Background: The MTP was rated by the manufacturer for operation on 110-120 VAC/50-400 Hz. Past experience indicates that some medical equipment tends to overheat when subjected to prolonged use, especially when using 400 Hz. We elected to determine the MTP's ability to withstand sustained 400 Hz use in the laboratory.

2. Setup: Monitoring was accomplished by the following methods:

- a. The MTP outside casing was removed, exposing the battery assembly.

b. Wires 22 awg x 24 in. were attached, 1 to the positive and 1 to the negative battery terminals. The other ends of the wires were fed through an opening in the casing, and the casing was reinstalled.

c. The other ends of the wires were attached to a Grant Squirrel Meter/Logger, Model 1201 for voltage reading and logging.

3. Method: Using the Squirrel, with a temperature sensor attached directly to the surface of the MTP charger, and logging the temperature every 5 min, the MTP was operated continuously for 30 h. The pump was run at a flow of 200 ml/h. An additional probe was used to monitor the temperature of the ambient air around the MTP.

4. Equipment Used:

- a. Basic Test Setup
- b. Grant Squirrel Meter/Logger
- c. Wires from MTP battery to Squirrel
- d. Temperature Probe

RESULTS

Baseline Performance Assessment

1. Qualitative Tests: The following discrepancies were found during the Baseline Performance Assessment (BPA):

a. Chassis/Housing - Front panel assembly "O" ring, part # 658000, was broken with a 15.24-cm (6-in.) piece missing. No missing portion was found within the unit, indicating it was received in this condition. Removal or insertion of the chassis from the case was very difficult. The handle screws extended into the chassis removal path. Extreme care was needed to prevent damaging the front panel during assembly/disassembly.

b. Mount - Did not fit the circumference of a standard NATO litter pole.

c. Circuit Breaker/Fuse - The line power fuse was not easily accessible. Occasionally, safety factors and prudent engineering judgment dictate an internal fuse. However, aeromedical equipment is subjected to more physical and electrical transient stresses that cause fuse failure, i.e., electrical power spikes or a physical bumping, than its stationary counterpart. These transient stresses will render the device useless until returned to a maintenance facility, which may be hours or days away. Therefore, a user accessible fuse and replacement or circuit breaker is highly desirable. Either option would allow the user a chance to continue operation. Recommendation: Inquire about a fuse that can be replaced by users.

d. Tubing - During the occlusion tests and sometimes during normal IV tubing setup, using the manufacturer's instructions, the IV tubing leaked a small amount of fluid at the clear outlet connector, apparently due to back pressure.

e. The power connector (Amphenol #206060-1) located on the unit's rear panel should have a safety screw installed to prevent turning the strain relief hub. The connector has 2 main portions: the strain relief hub and the pin housing. Both portions have a grooved circumference for gripping and turning. Turning the pin housing will correctly remove the connector from the unit. However, turning the strain relief hub twisted and disconnected the electrical power wires, causing an electrical safety hazard. If undetected, this hazard causes the unit to operate on battery. This hazard, compounded by the lack of a battery condition indicator, a 10-min low battery warning, and a very small charging indicator which was difficult to see in a well-illuminated room, is likely to cause future problems.

2. Infusion Range and Accuracy: The required infusion range specified in the contract was 1-700 ml/h. The unit delivered between 1-499 ml/h. Table 1 illustrates the volume infused accuracy.

TABLE 1. VOLUME INFUSED ACCURACY

SET VOLUME (ml/h)	ACTUALLY MEASURED (ml/h)	ERROR (In %)
005	004.8	0.0
010	009.7	3.0
020	019.4	3.0
050	048.2	1.6
100	096.4	3.6
200	191.0	4.5
300	289.0	3.6
400	386.0	3.5
499	484.6	2.9

3. Flow Error Change During 22 h of Operation: The flows are listed below. Total volume infused after 22:15 (h:min) was 3,380 ml. The displayed volume infused was 3,361 ml and the calculated volume (ml/h x h) was 3,360, which deviates 0.56% and 0.59% from the actual measured volume. These measurements were made during the battery operation test (post 110 VAC/60 Hz charge).

Results: Acceptable. Meets the flow accuracy of $\pm 5\%$.

**TABLE 2. FLOW RATE DURING 22-h OPERATION
PERIOD (RATE: 150 ml/h)**

HOURS OPERATION (h:mln)	FLOW MEASURED (ml/h)	ERROR (ln %)
12:05	149.6	0.26
16:08	149.6	0.26
22:11	150.0	0.00

4. **Electrical Safety:** The ground resistance was 80 milliohms at a single screw located at the power line connector. All other metal surfaces were above 800 milliohms (500 milliohms is the maximum allowed). The chassis leakage current was 2 μ A with the ground intact, 8 μ A with the ground open, and 9 μ A with ground open/reversed polarity. Note: The ground resistance problem was then resolved.

5. **Alarms:**

a. **Air-In-Line:** Alarm activated 4 out of 5 times tested. Air bubble separation may have caused the single nondetection.

b. **Infusion Complete:** Alarm activation and volume infused were exact. The KVO rate was verified to be 1.0 ml/h with the flow between 5-499 ml/h and 0.5 ml/h when set below 5.0 ml/h, as specified in the manufacturer's literature.

c. **Occlusion:** Alarm activation occurred at pressures of 21.5, 23.2, and 24 psi (contract specifies 6-16 psi) at flows of 20, 100 and 200 ml/h, respectively. Also, occlusions between the IV bag and pump may go undetected until the "AIR" alarm is activated. The flow stopped after infusion of 1-3 ml, but the pump continued to rotate and display inaccurate infused volumes between 18.9 and 66.3 ml/h, depending on the flow (the higher the flow, the greater the inaccuracy). During subsequent testing, the calibration of the MTP was eventually adjusted so that the MTP alarmed after a satisfactory interval, and at a satisfactory pressure.

d. **Low Battery (Battery Operating/Charging Characteristics):** During this test, the low battery alarm activated after 25:09 h operation. Infusion continued for approximately 10 min before the "BAT," "KVO," and amount infused were alternately displayed. The charging light-emitting diode (LED) indicator remained illuminated under these conditions and whenever the unit was plugged into line power. Low battery alarm activates with 10 min of operation remaining.

6. **Summary:** The IV pump failed in 2 areas, IV administration set fluid leakage and excessive ground resistance. These were major failures which required correction. Fluid leakage is an obvious hazard to patient and care provider, particularly when administering blood products. Excessive ground resistance is an electrical hazard and is easily resolved by insuring good electrical continuity between each metal surface on the pump. Note: Each of those failures was subsequently corrected.

Electromagnetic Interference

1. EMI testing was quite extensive. Various modifications were required to make the MTP electromagnetically compatible. A brief overview of the completion process follows:

a. During the first series of tests, the MTP failed radiated emissions narrow-band testing as follows:

(1) Operating the MTP on 60 Hz line power, failure at 35-300 kHz, 2.5 MHz, 29-30 MHz, and 50-75 MHz.

(2) Operating the MTP on 400 Hz line power, failure at 35-350 kHz, 2.5 MHz, 18-19 MHz, 28-30 MHz, 44-46 MHz, and 50-75 MHz.

(3) Operating the MTP on internal battery, failure at 35-200 kHz.

(4) Operating the MTP without an IV setup in place, on 60 Hz line power, failure at 19 MHz, 28-30 MHz, 49-83 MHz.

b. The MTP was returned to the manufacturer for modification. Over 2 months later, it was returned. During follow-up tests, the MTP again failed radiated emissions narrow-band testing as follows:

(1) Operating on 60 Hz line power, failure at 35-39 kHz, 30 MHz, and 40-58 MHz.

(2) Operating on 400 Hz line power, failure at 35-500 kHz, 0.78 MHz, 27 MHz, and 40-60 MHz.

(3) Operating on internal battery, failure at 35-390 kHz.

c. The MTP was returned to the manufacturer, followed by a lengthy series of discussions involving the manufacturer, 375th AAW/SGNL, and the Scott AFB contracting office, over a course of 4 months. During that time, the manufacturer consulted an outside EMI testing facility, Retlif Inc. Testing Laboratories, of Ronkonkoma NY for assistance in resolving the problems. At one point, representatives from MTP visited our facilities, accompanied by an engineer from Retlif, to discuss testing methods and possible fixes with our engineering and clinical staff.

d. Over 4 months after the previous return to the manufacturer, the MTP was returned for resumption of testing. A complete series of tests were performed, and this time the MTP passed EMI testing. The following steps describe the various modifications that eventually resulted in the MTP passing EMI:

(1) Shielded motor harness assembly.

- (2) Unpainted attachment locations for:
 - (a) Stepper motor.
 - (b) Round tubular front and back panel spacers (4).
 - (c) Power input connector.
 - (d) Normal ground connector.
- (3) Shielded power cable.
- (4) Shielded input/output transformer charger cable with attached ferrite beads.
- (5) AC to unregulated DC transformer.
- (6) Metal power input connectors.
- (7) Filters attached to the power input leads.
- (8) Filter box over the pump's input power connector.
- (9) CMOS E PROM instead of stock CPU -- HMOS E PROM.

e. While trying to identify the source of the remaining EMI problems, it was discovered that when the unit was turned off, and the pump roller head assembly turned by hand, there were still emissions that seemed to cause EMI failure. The IV tubing was removed from the MTP, and by digitally rubbing the tubing the same emissions were detected by the EMI recorder. It was determined that the emissions were caused by a static buildup on the tubing. After discussion with ASD/ENACE at Wright Patterson AFB OH, it was determined that the emissions caused by the static on the tubing were not in a frequency range that would interfere with navigation or communication equipment on the aircraft. The pump passed EMI with the modifications previously listed.

Vibration

a. During the first series of vibration tests, the Y-axis, sinusoidal and random, were completed without any problem. However, during X-axis random testing, the MTP's LED display failed. Investigation revealed the bracket that secures the battery assembly broke in 2 places, allowing the battery assembly to bounce around inside the MTP. The battery was destroyed. Another problem was the power cable wires had been pulled loose from the screw connections at the back of the MTP. See Figs. 5, 6, and 7. As a result of these problems, the MTP was returned to the manufacturer for repairs.

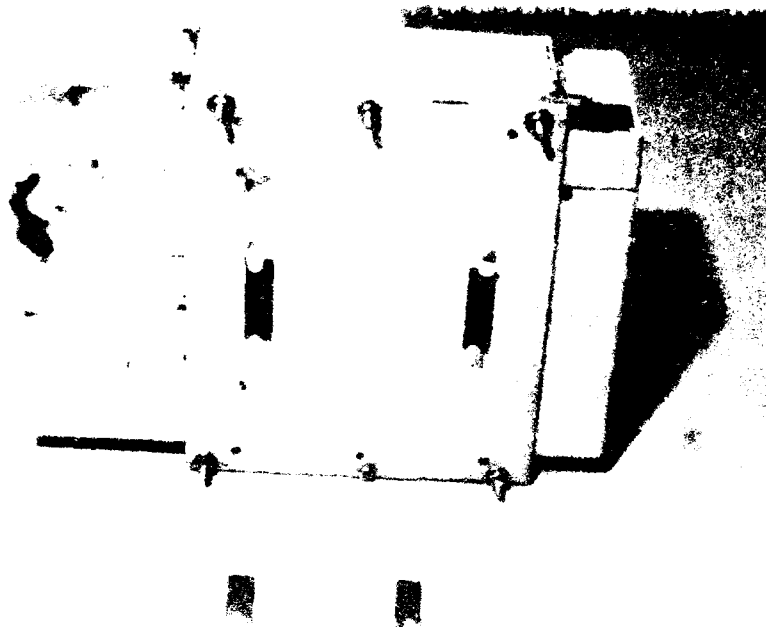


Figure 5. Battery bracket following initial vibration.



Figure 6. Battery assembly following initial vibration.



Figure 7. Power cable assembly following initial vibration.

b. Upon return of the MTP from the manufacturer, vibration testing was resumed; starting with the Z-axis, using 110 VAC/60 Hz for operation and charging during the tests. Sinusoidal was completed without problem. However, during random the charge light started blinking. The unit continued to operate satisfactorily. When examined by medical maintenance personnel following conclusion of the Z-axis, they found a broken capacitor, part #601014. In telephone conversation with the manufacturer, it was agreed that our maintenance personnel would replace the part, rather than sending the unit back to the company. After 5 days of attempting to locate the part locally, maintenance personnel tried to repair the broken part by soldering. Following this repair, the unit was plugged in for charging. The repair was unsuccessful. After being plugged in for a 24-h charge, the battery was still dead.

c. A week later the capacitor and a new battery were received from the manufacturer. Once installed, the MTP including the battery and charger seemed to work satisfactorily. Once again vibration testing resumed, again starting with the Z-axis, followed by X and Y, with the unit plugged in for charging and operation during the tests. The unit performed satisfactorily during this series of tests, and seemed to have finally passed the complete series of vibration tests. However, 2 days later, while attempting to set up the unit for altitude testing, using battery power, the MTP was inoperable. The unit was examined by maintenance personnel, who found the battery totally discharged. Maintenance found that the charging circuit and low battery alarm circuits did seem to be working. They determined that either an electrical short had drained the battery; or more likely that the last series of vibrations had damaged the battery. Engineers from the manufacturer thought the problem was with the particular make and model of battery used, and proposed that they be allowed to submit a different battery.

d. A different battery was sent. All previous batteries were returned to the manufacturer. The new battery, Model PS 6100, was installed. Wires were attached to the terminals, fed through the back of the unit and attached to the Grant Squirrel Model 1201 Meter/Logger for voltage measurement. All other testing was conducted while closely monitoring the voltage.

e. With the new battery, the complete series of vibration tests were conducted. The MTP passed each of these tests.

f. Additional findings and observations during vibration testing:

(1) Infusion Rate: The MTP infused extremely accurately on all 3 vibration axes, when set at 50 and 150 ml/h (Figs. 8 and 9). When set at 499 ml/h, however, the unit delivered at excessively high rates about half the time. This rate was first noticed while vibrating on the Z-axis (Fig. 10). Shortly after starting on the X-axis, with the same results, the volumetric chamber was changed to the larger size, Model 404-35A. For the rest of the X axis and all the Y-axis, the MTP's infusion rate was extremely accurate (Fig. 11).

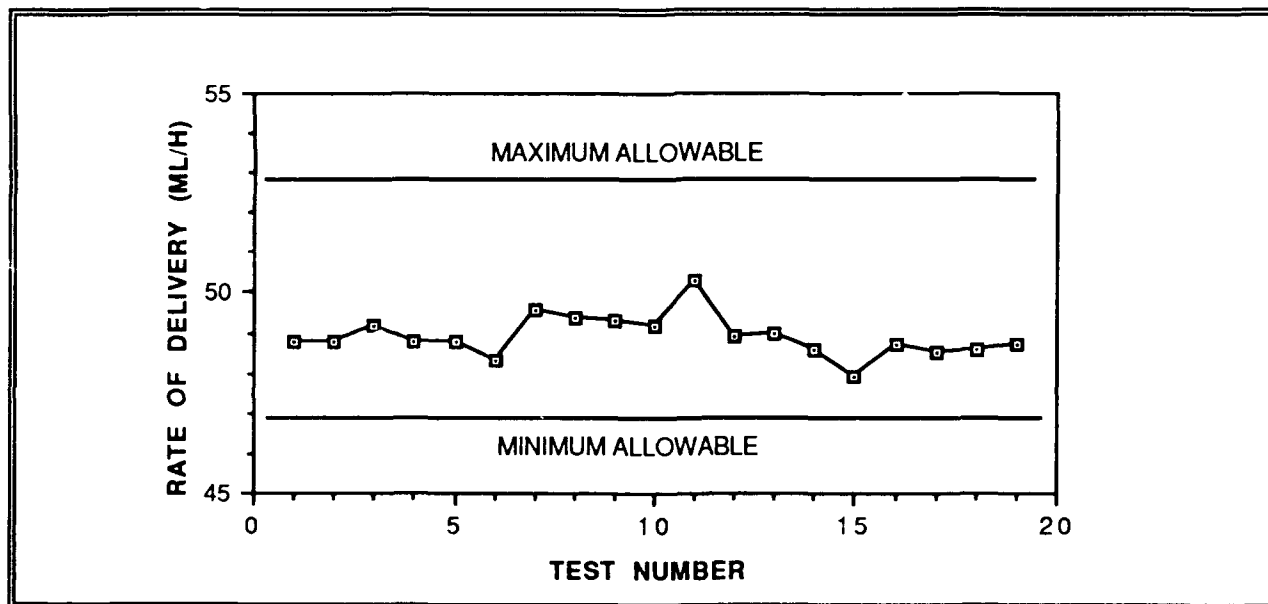


Figure 8. MTP Delivery Set at 50 ml/h During Vibration Testing

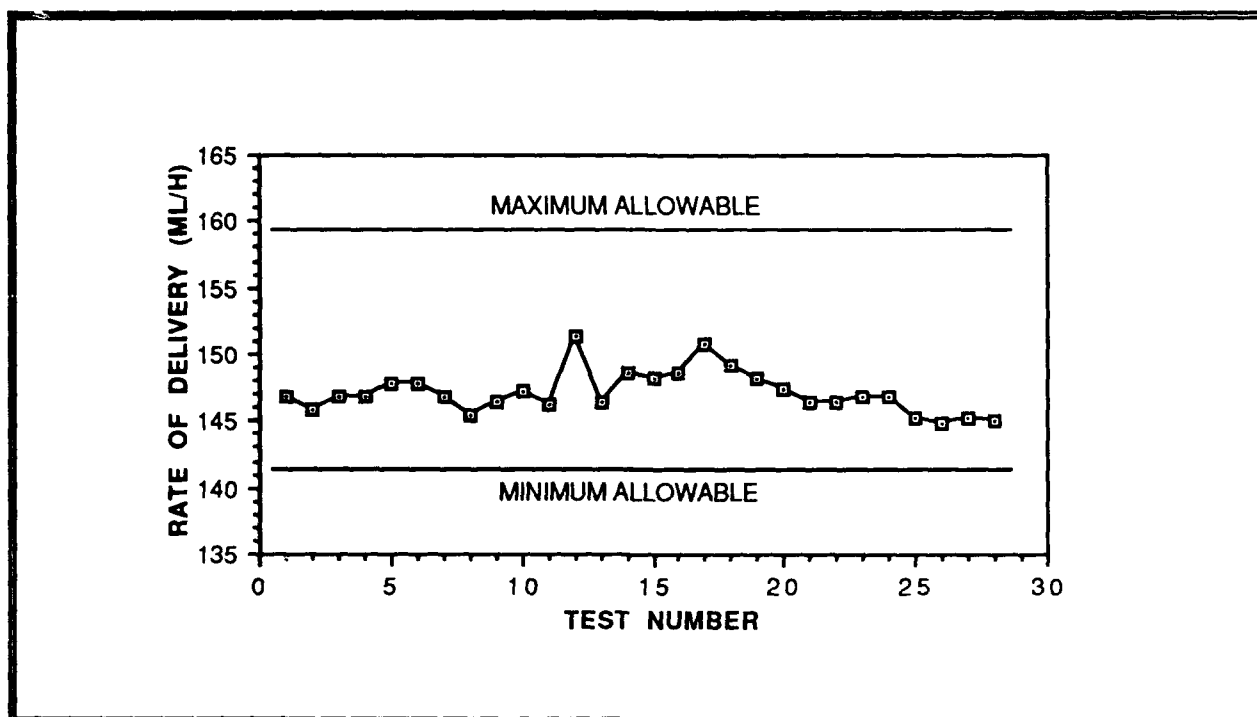


Figure 9. MTP Delivery Set at 150 ml/h During Vibration Testing

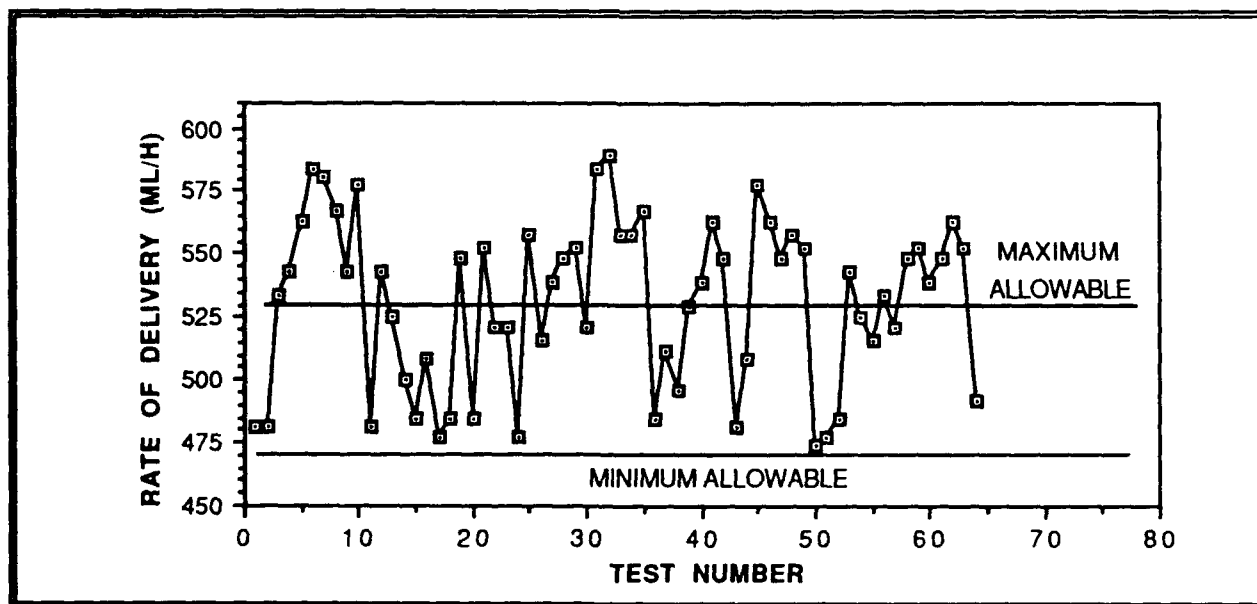


Figure 10. MTP Delivery Set at 499 ml/h During "Z" Axis.

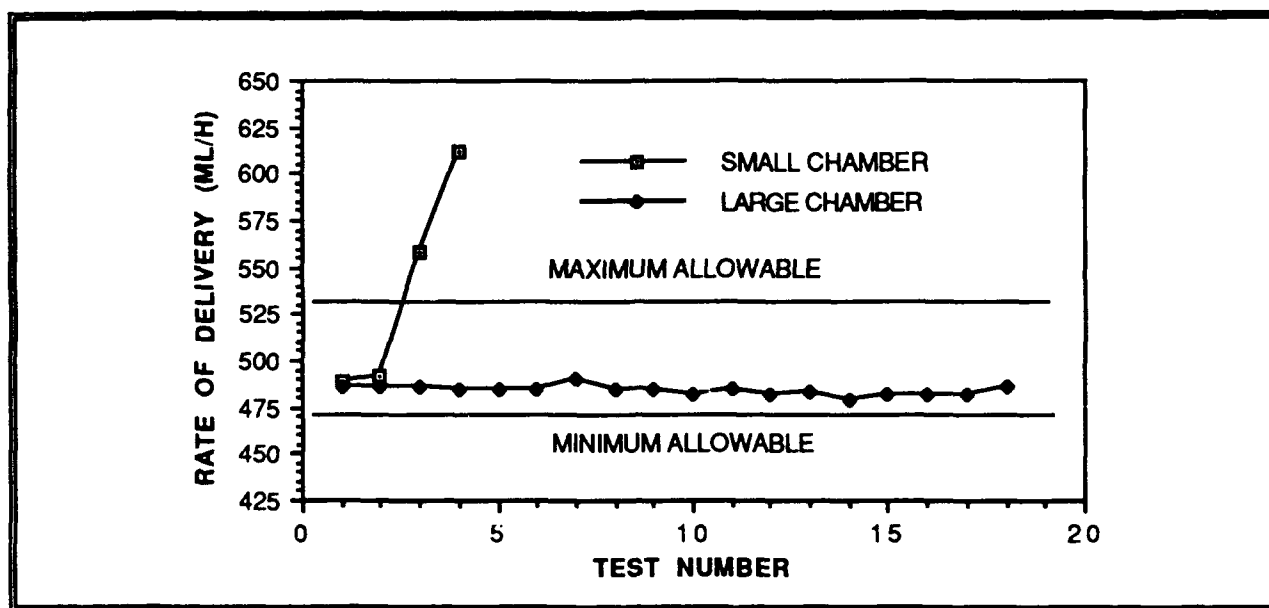


Figure 11. MTP Delivery Set at 499 ml/h During "X" & "Y" Axes.

(2) Volume Infused (Running Total): Actual volumes infused were as indicated on the MTP display, $\pm 1\%$.

(3) Total Volume To Be Infused: The MTP entered the KVO mode, as required, when a preset total volume had been delivered.

(4) Keep-Vein-Open Rate: Once the preset total volumes to be infused had been achieved, the MTP automatically changed to the KVO mode and infused at flows of 0.5 ml/h if the previous rate had been less than 5.0 ml/h, and 1.0 ml/h if the previous rate had been 5.0 ml/h or higher.

(5) Air-In-Line Alarm: Results were inconclusive. Too often the injected bubble would break up into smaller bubbles before reaching the bubble sensor.

(6) Occlusion Alarm: Results were inconclusive. Too often the tubing leaked when occluded, making it impossible for the post-pump portion of the tubing to build up adequate pressure to activate the alarm. By the time satisfactory replacement tubing had been obtained, vibration testing had been completed. The leakage was attributed to defective tubing.

(7) Mounting Bracket: The mounting bracket, which includes a vise-type clamp, became ineffective before the conclusion of testing. Specifically, the large threaded shaft, which attaches the MTP to the litter pole, wore out. It became very difficult to turn the shaft by hand with enough force to effectively secure the MTP to a litter. On the last occasion when it was used in this condition, even when tightened to the maximum degree using pliers, it still was not tight enough to prevent the MTP from rotating more than 90° from an upright position to a position where the front of the MTP was facing the floor. Removal was even more difficult. Again, pliers were often required to loosen the shaft. When notified, the manufacturer supplied us with another

mounting bracket assembly, and there were no further problems with this throughout the conclusion of testing. It is anticipated that users will eventually experience the same problem.

Altitude

1. Hypobaric Chamber Testing:

- a. Infusion Rate: Infused at accurate rates.
- b. Volume Infused (Running Total): Displayed an accurate running total.
- c. Total Volume To Be Infused: Delivered the preset volumes and entered the KVO mode .
- d. Keep-Vein-Open Rate: Delivered as specified.
- e. Air-In-Line Alarm: Table 3 shows the dependability of the air bubble detector, which activates the air-in-line alarm. While these results were compiled from testing at altitude, they typify the results when tested under other conditions.

TABLE 3. DEPENDABILITY OF AIR-IN-LINE DETECTOR AT 10,000 FT ALTITUDE.

RATE	BUBBLE SIZE (ml)	# OF SAMPLES	# OF ALARM ACTIVATIONS	% OF ACTI- VATIONS
050	0.050	8	0	0
050	0.075	30	22	73
150	0.050	30	9	30
150	0.075	30	26	87
150	0.100	4	4	100
499	0.050	30	12	40
499	0.075	30	20	67
499	0.100	4	4	100

(1) 0.050 ml: The MTP cannot be depended on to detect air bubbles of this size or smaller.

(2) 0.075 ml: The MTP is usually dependable for detection of air bubbles of this size.

(3) 0.100 ml: The MTP can be depended on to detect air bubbles of this size or larger.

f. Occlusion Alarm: During occlusion tests, some tubing leakage was noted. When no leaks occurred, the MTP performed satisfactorily.

2. Rapid Decompression: The MTP performed satisfactorily during, and after each rapid decompression.

Airborne Feasibility

1. Performance Checks:

- a. Infusion Rate: Infused accurately.
- b. Volume Infused (Running Total): Provided accurate running total.
- c. Total Volume To Be Infused: Alarmed and switched to KVO rate when preset total volume had been attained.
- d. Keep-Vein-Open Rate: Delivered at specified rate when in KVO mode.
- e. Air-In-Line Alarm: Satisfactorily detected air bubbles, 0.075 ml or larger.
- f. Occlusion Alarm: Except when the tubing leaked, the MTP consistently alarmed, and stopped pumping when tubing was occluded.
- g. Voltage: Workable voltage maintained for up to 30 h, during battery operation.

2. Other Findings, Resulting from Completion of Airborne Feasibility Checklist:

- a. Carrying Case: The case, while structurally sound, is too large--50.5 cm x 38.1 cm x 25.3 cm (20 in. x 15 in. x 10 in.)--for the relatively small MTP. Four MTPs, with adequate padding, could easily fit in the case. The case lid should be hinged, rather than completely removable.
- b. Mounted On NATO Litter: While the MTP can be mounted on the litter, it should not be done for patient movement. The MTP's protrusion presents a safety hazard, if mounted during litter/patient movement.
- c. Tubing Length: Due to the limitations of the Model 1200 tubing, the MTP should be mounted within 1.5 m (5 ft) of the patient's IV access site.
- d. C-9 Mounting Locations: With the MTP mounted at waist level, the power cord, 1.75 m (69 in.), was not long enough when mounted on the foot end of litter tier TR-1 and TL-1. At all other litter tiers, the MTP could be mounted at either the head or foot end. Other acceptable locations on the C-9 were as follows:
 - (1) Using the Aeromedical Equipment Securing Pole, clamped in a cantilever arm (the preferred method). See Figure 12.
 - (2) ALSS incubator handle.
 - (3) Mounted sideways on litter stanchion.
 - (4) On overhead console, with litter strap looped through MTP handle for added safety.

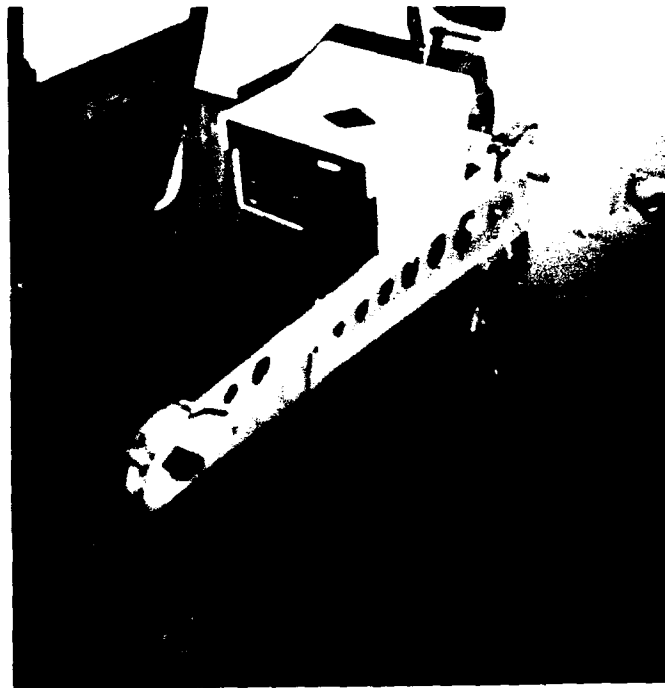


Figure 12. Mounting on the C-9 aircraft using the Aeromedical Equipment Securing Pole.

(5) On NATO litter.

(6) On cantilever arm.

e. Acceptable C-141 Mounting Locations:

(1) Using the Aeromedical Equipment Securing Pole, clamped in a litter bracket on a stanchion (the preferred method). See Figure 13.

(2) On NATO litter.

(3) On Evans seat rail, with strap looped through MTP handle for added safety.

f. Visibility: Depending on lighting, the MTP's indicators and alarms could be seen from distances 9.14-12.19 m (30-40 ft) away.

g. Audible Alarms:

(1) C-9A: Alarms could be heard from anywhere in the cabin from 3.05-3.66 m (10-12 ft) away.

(2) C-141B: Alarms could only be heard if the ear was placed flat on the surface of the MTP.

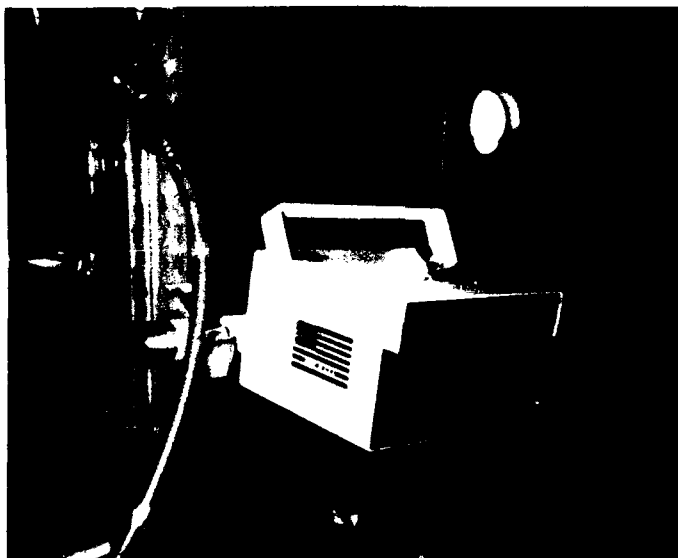


Figure 13. Mounting on the C-141 aircraft using the Aeromedical Equipment Securing Pole.

3. Other Findings:

a. Leaky Tubing: An excessive number of IV tubing sets, Model 1200, leaked during various phases of airborne testing, usually during occlusion tests. This leak was determined to be unrelated to the airborne environment, and it was decided that a follow-up evaluation of the tubing could and would be conducted on the ground.

b. Direct Observation on C-141B: The MTP cannot be observed from any crewmember's seat. Due to the limitations of mounting locations in the C-141 litter section, if continuous direct observation of the MTP is critical, then a crewmember must stand up near the MTP for take-off and landing.

c. Soft Case: If the soft padded nylon case is to be used for carrying the MTP, a handle should be added, so that it can be carried with 1 hand.

Battery and Charging Testing

Typically, following a charge of 24 h on 110 VAC, the MTP ran on battery power for about 30 h. At that point the MTP would activate the "BAT" alarm, and the voltage would be about 5.75. See Figures 14 and 15.

Operation on 400 Hertz

During 8 h of operation on 400 Hz, there was no significant increase in transformer temperature, as shown in Figure 16.

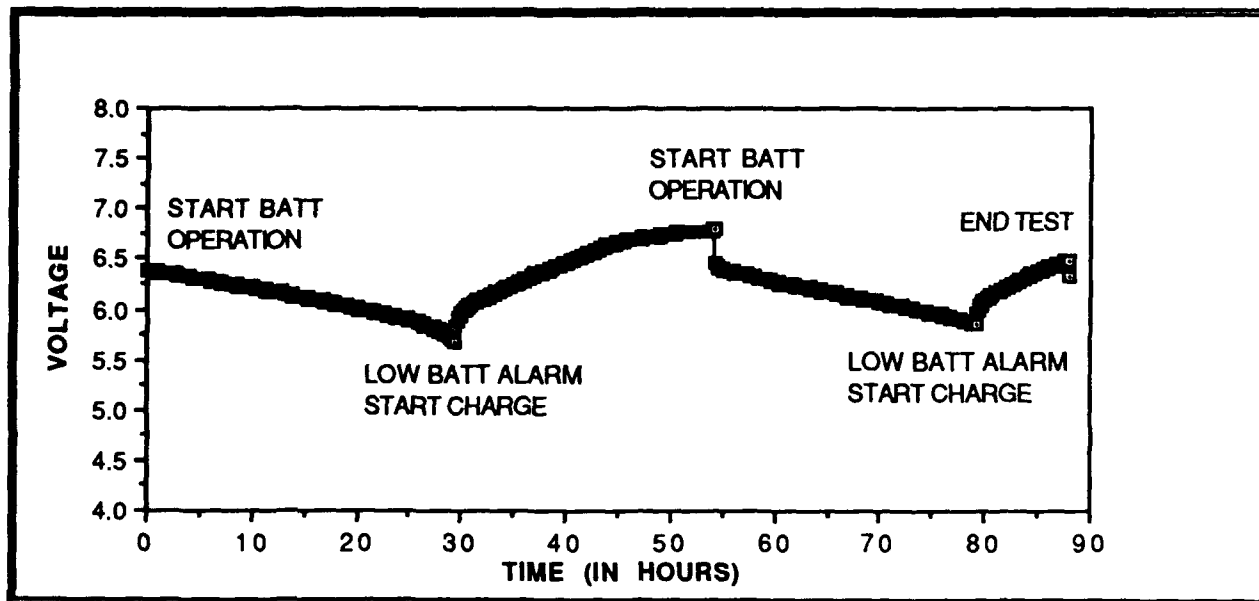


Figure 14. Voltage during battery operation and charging on 110 VAC.

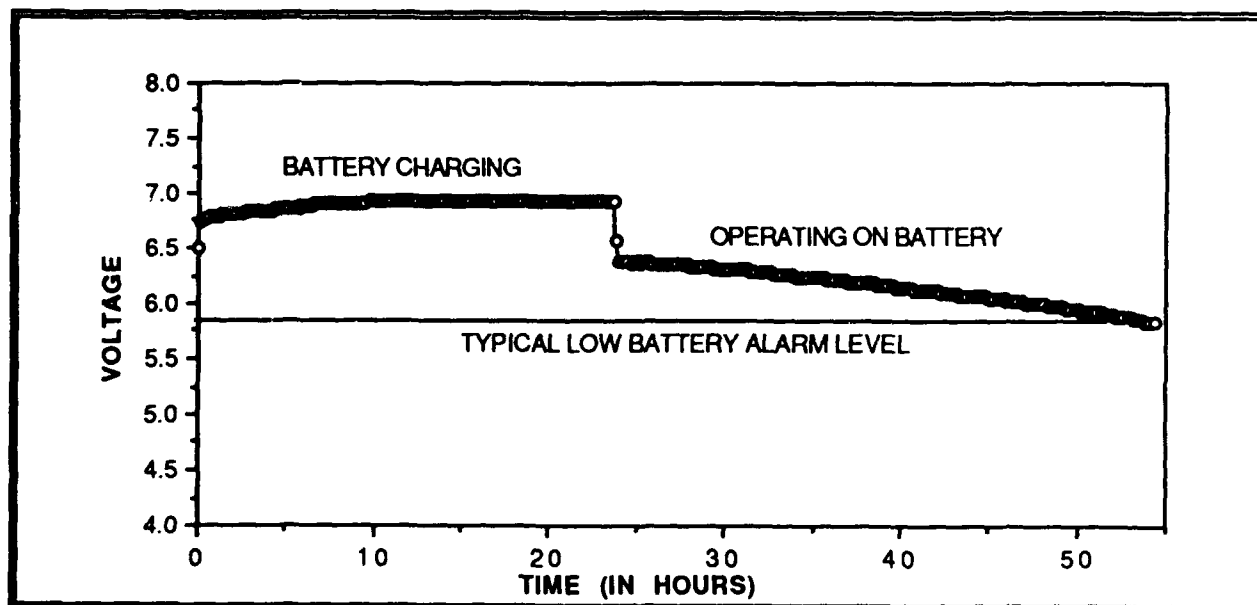


Figure 15. Voltage during battery operation and charging on 110 VAC, post rapid decompression testing.

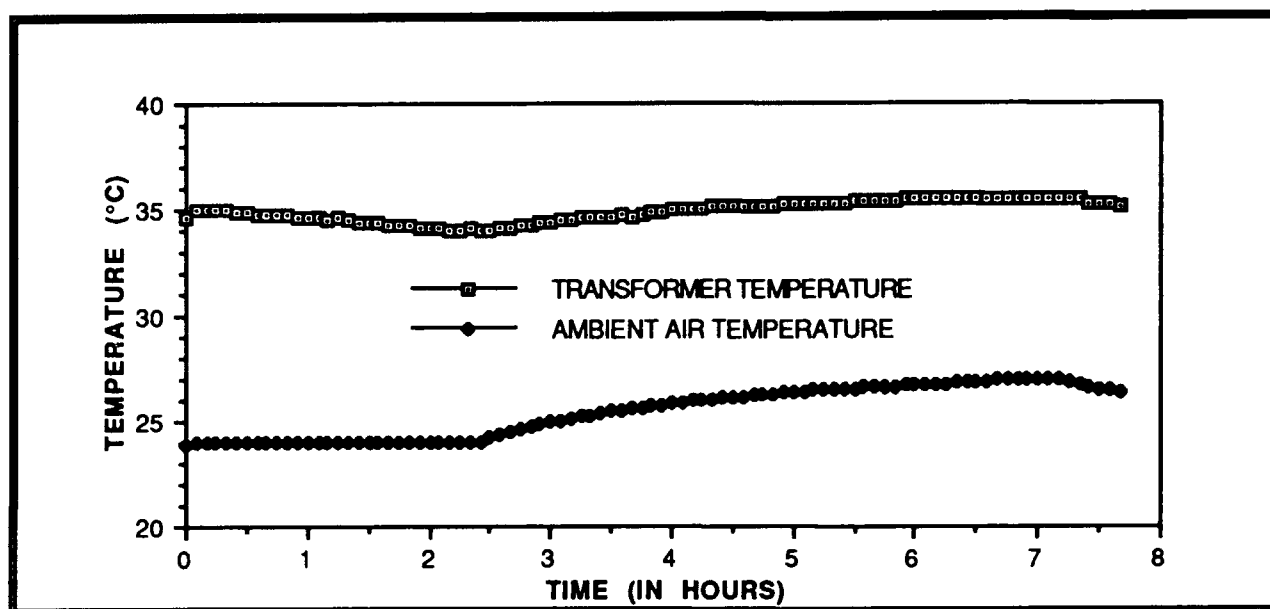


Figure 16. Temperature of transformer/charger during 400 Hz operation.

REQUIREMENTS AND RECOMMENDATIONS

1. Members of the 375th MAW Surgeon's staff at Scott AFB IL were briefed on the testing and evaluation of the MTP Model 1001a, on 13 April 1990. Test results, findings, observations, requirements, and recommendations for its use were discussed, along with a hands-on demonstration of its operation.

2. In addition, a written interim report (8) was submitted on the same day. The following paragraphs list the requirements, recommendations and observations briefed and reported to the 375th MAW personnel:

a. Requirements:

(1) The 1001A Service Manual (9) does not contain current calibration procedures. A 325 ml (11 oz) weight should be used during the motor voltage calibration instead of the 384 ml (13 oz) weight referenced in the current manual, page 18 paragraph 3. Also, voltage adjustments are made using resistor R15, instead of R51 as stated on page 18, paragraph 2. The manual must be corrected to reflect the current calibration procedures.

(2) Modifications to the 1001A must be made as follows:

(a) EMI: As described in MTP letter dated September 13, 1989 (10).

(b) Battery: The unit must be provided with the PS6100 battery, which satisfies electromagnetic compatibility, vibrational, and duration requirements.

(c) Battery Bracket: The bracket securing the battery to the inside of the 1001A must be reinforced with additional screws, as was done with the test unit.

(3) MTP manufactures a complete line of tubing to be used with the 1001A. Three separate models were evaluated. Model #1201 was found to be unacceptable due to fluid leakage and tubing separation. Model #1200 (Lot #H264801) had the same unacceptable characteristics. However, when notified of this problem, MTP submitted a case of a later edition of Model #1200 (Lot #MV2289) for testing. The later edition proved to be acceptable, with no evidence of leakage or separation. The older 1200 is packaged with paper on 1 side and peel-away clear plastic on the other side. The tubing itself has a red vent cap on the drip chamber, and a blue cap covering the patient end of the tubing. The newer 1200 is packaged with a clear plastic bag. The tubing itself has an opaque vent cap on the drip chamber, and a clear cap covering the patient end of the tubing. It is important that the older 1200 not be used. **WARNING: Using the older 1200 tubing could result in tubing separation with no alarm activation, which could endanger the patient!** Due to this malfunction, only the newer lots of Model 1200 are acceptable for use with the 1001A. No other models of tubing have been tested and/or found acceptable for use.

(4) The power line/transformer assembly screws to the back of the 1001A. To avoid an electrical short or shock when plugging in to AC power, the following steps must be taken:

(a) Ensure that the 1001A power switch is turned off.

(b) Attach the transformer to the back of the 1001A, using the clip hook. Screw the power line to the back of the 1001A.

(c) Plug in the power line to AC power.

b. Recommendations:

(1) Mounting:

(a) Do not mount on a litter for enplaning or deplaning.

(b) The unit should be mounted within 1.52 m (5 ft) of the patient, due to tubing length limitations.

(c) On the C-9, C-130, and C-141 aircraft, it is recommended that the Aeromedical Equipment Securing Pole, which tightly clamps into a cantilever arm or litter bracket, be used for securing the 1001A. A prototype was provided for 375 AAW/SGNL in December 1989. When used on the C-9, a separate cantilever arm should be used for the unit placed in close proximity to the patient litter.

(d) On the aircraft, particularly the C-141, the alarms are inaudible. If possible, mount the 1001A so that it can be viewed by a crewmember. On the C-141 there is no known securing method that will allow observation of the unit

from a crewmember's seat. If observation or monitoring for alarm conditions is critical, then a crewmember should stand with the unit for takeoff/landing.

(2) When fully charged, the 1001A will normally run on battery power for 24 to 30 h. A full charge takes up to 24 h plugged into the AC power supply; however, there is no full-charge indicator. For that reason, whenever possible during use and nonuse, the unit should be plugged into AC power.

(3) The mounting bracket assembly includes a long screw with a turning rod connected to the top. After prolonged use, there is a tendency toward thread deterioration and bending of the turning rod. Crewmembers should be aware of this. It is also recommended that the manufacturer strengthen the turning rod, and possibly attach some rubber to the jaws of the clamps to reduce the degree of torque required to safely secure the 1001A.

(4) Carrying case:

(a) The carrying case seems too large for the relatively small 1001A. A similar case, but about half the size, should be considered.

(b) If the same case or same type case is used, the lid should be hinged rather than completely removable.

(5) After electromagnetic emission testing, it was noted that the **power (brown) and neutral (blue) wires were reversed**. Maintenance personnel should be aware that the 1001A AC power cord is wired using European color coding. If maintenance personnel are unaware of this incorrect connection, it could result in equipment damage or electrical shock to personnel.

(6) During the course of our evaluation, many of the problems preventing completion involved EMI. The manufacturer eventually resolved the EMI problems with considerable modification. To ensure that units purchased in the future are modified, it is strongly recommended that before Operational Testing and Evaluation (OT&E), the 5 additional units used for OT&E be submitted to USAFSAM for EMI testing. Note: The 5 additional units were submitted and did pass EMI testing.

(7) When the soft case is applied, the unit's carrying handle is not accessible. If the soft case is used, a carrying handle or strap should be added.

(8) The flow and total volume controls have 2 sets of digital switches marked "+" and "-" for increasing or decreasing the rate or volume. The pluses and minuses are extremely difficult to see. Also, the set of **pluses** are located **under** the digital display, while the set of **minuses** are **over** the display. This location leads to confusion which can be alleviated by placing large white decals indicating plus or minus by each set of switches.

c. Observations:

(1) While using the Aeromedical Equipment Securing Pole is the **recommended** method for mounting the 1001A, other methods were evaluated and found to be satisfactory:

(a) While **not recommended** due to protrusion into the walkway, on any aircraft, the unit may be mounted on the side of a litter.

(b) The unit may be mounted on the handle of the ALSS incubator.

(c) On the C-9, the unit may be turned sideways, and mounted on the litter stanchion. It may be mounted on the narrow end of the cantilever arm. Also, for ambulatory patients, it may be mounted on the overhead console, with a strap in place as an additional safeguard against falling.

(d) On the C-9, in litter tiers TR1 and TL1, the unit's power cord will reach AC outlets only if mounted at the head of the litter. In other tiers, the unit may be mounted at either the head or the foot.

(e) On the C-141, for ambulatory patients, the unit may be mounted on the Evans seat rail, if a strap is used to prevent falling and rotation on the rail.

(2) The contract specifications state that the infusion pump must detect air bubbles 0.05 ml or larger. The 1001A is unable to consistently meet that specification. However, the detector will consistently detect bubbles 0.07 ml or larger, as specified in the operator's manual.

(3) The manufacturer has verbally stated that the 1001A may be used for tube feeding. However, this capability was not evaluated, and there is no mention of tube feeding in the company's literature.

CONCLUSIONS

Test results were reviewed by members of the Aeromedical Research Function, consisting of a flight surgeon, a flight nurse, 3 biomedical engineers, and 2 aeromedical evacuation technicians. It was concluded that provided requirements listed in the previous section are met, the MTP Model 1001a infusion pump is a safe, effective, and reliable device for the delivery of intravenous fluids, and acceptable for worldwide aeromedical evacuation use.

ACKNOWLEDGMENTS

I would like to thank those who helped and advised me during the evaluation of the MTP Model 1001a infusion pump. I would particularly like to thank:

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Capt Susan Nagel
1Lt Rebecca Schultz
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MSgt Ernest Roy
MSgt Victor Elizondo
TSgt R. J. Van Oss
SSgt Steve Simon
SSgt Thomas Waters

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